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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,957

02/18/2005

Robert Petrosenko

7175-71861

1060

23643 7590 09/30/2008
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EXAMINER

BOGART, MICHAEL G

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

09/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,957	Applicant(s) PETROSENKO ET AL.	
	Examiner MICHAEL G. BOGART	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-16,19,23-25 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-16,19,23-25 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/10/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 August 2008 has been entered.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 12 and 23 are rejected under 35 U.S.C. § 102(a) as being anticipated by Lockwood *et al.* (US 2002/0065494 A1; hereinafter: “Lockwood”).

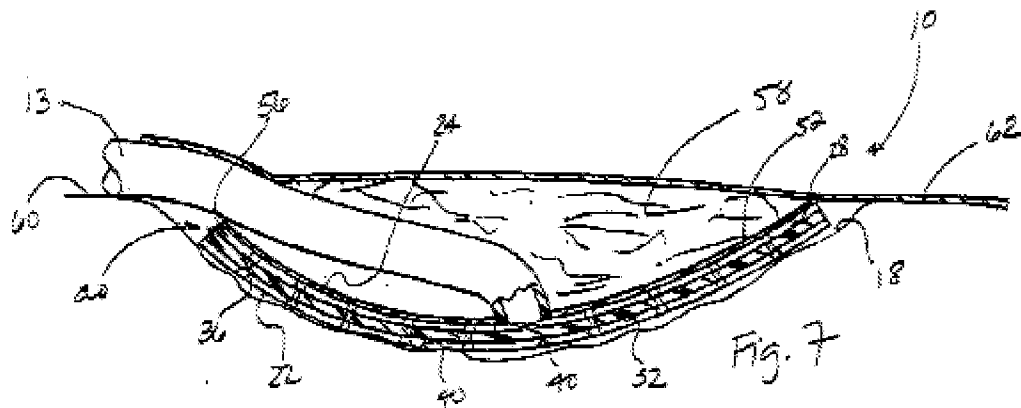
Regarding claim 1, Lockwood teaches a vacuum bandage system (10, 12) capable of being used with a wound (16) having a wound surface, the vacuum bandage system (10, 12) comprising:

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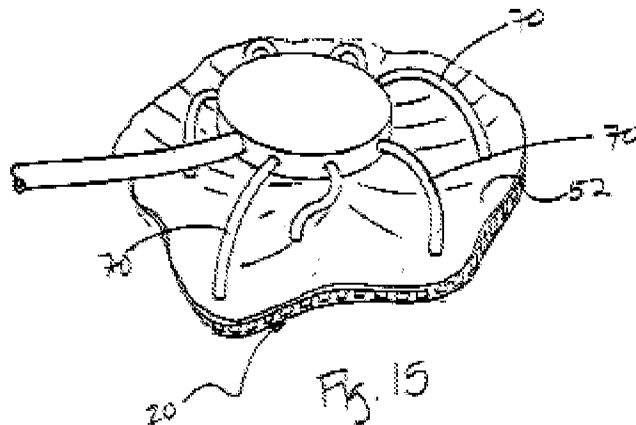
a wound dressing member (52) made generally of a non-porous material having a plurality of holes and a port (70) in communication with the holes and capable of being coupled to a vacuum source (12), and a wound insert (20) capable of being placed within the wound (16) between the wound surface (18) and the wound dressing member (52), the insert (20) being made of a material which is not porous or foam-like, and

a cover (62) capable of placement over the wound dressing member (52) to seal about the wound (16) and create a sealed environment between the wound (16) and the cover (62) in which negative pressure can be established (§ 0031)(see figures 7 & 15).

Regarding claim 2, Lockwood teaches that insert (20) is made of medical grade silicone (§ 0031).



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Regarding claim 3, Lockwood teaches that the wound insert (20) includes a plurality of discrete passageways (28, 30, 32, 34, 36) in communication with the vacuum source (110).

Regarding claim 4, Lockwood teaches that the passageways (28, 30, 32, 34, 36, 56) are conduits through the wound insert (20).

Regarding claims 5 and 12, Lockwood teaches an insert (20) that includes a top surface (24), a bottom surface (22), and a side surface, and wherein the conduits (56) form holes or bores in one or more of the side surfaces, and wherein the insert (20) further includes holes (36) in communication with the conduits (56) and forming holes (36) in one or more of the top and bottom surfaces (22, 24)(see Lockwood, fig. 7, supra). Further regarding claim 12, Lockwood teaches a thin flexible member (20) spaced away from the suction tube having bores (36) extending from the top to bottom surfaces (22, 24)(see fig. 15).

Regarding claims 6 and 7, Lockwood teaches channels (28, 30, 32, 34) in each of the top and bottom surfaces (22, 24) and holes (36) between the channels (28, 30, 32, 34).

Regarding claim 23, Lockwood teaches a wound insert that is capable of preventing an ulcerated portion of a wound from forming a bridge to another ulcerated portion of the wound.

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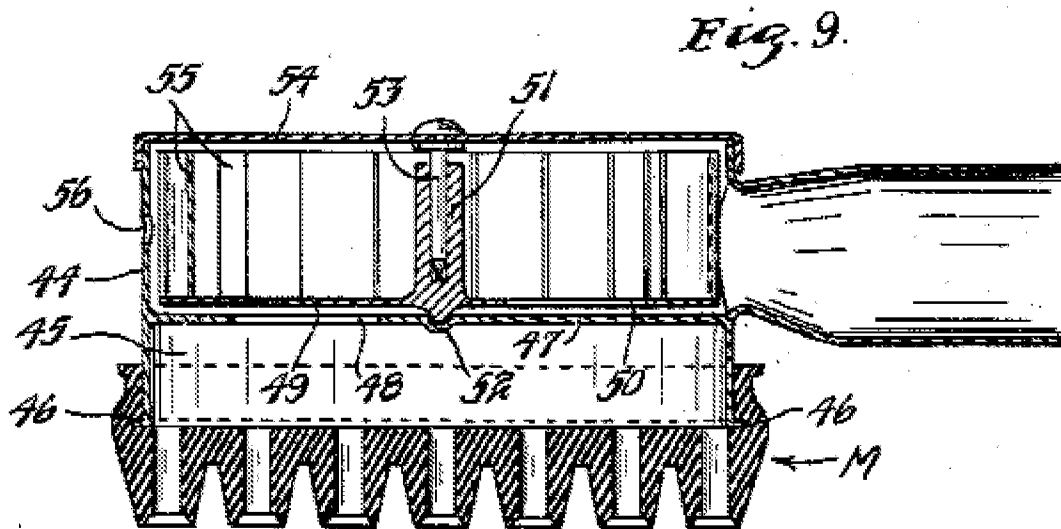
Claims 1, 13, 14, 16, 19, 23-25 and 27-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by La Mere *et al.* (US 2,338,339; hereinafter “La Mere”).

Regarding claim 1, La Mere teaches a vacuum bandage system (11, 12, 13) capable of being used with a wound having a wound surface, the vacuum bandage system (11, 12, 13) comprising:

a wound dressing member (44) made of a generally non-porous material and is capable of contacting a wound having a plurality of holes (48, 50, 56) and a port (15) in communication with the holes (48, 50, 56) and capable of being coupled to a vacuum source (11), and a wound insert (M) capable of being placed within the wound between the wound surface and the wound dressing member (44), the insert (M) being made of a material which is not porous or foam-like (rubber), and

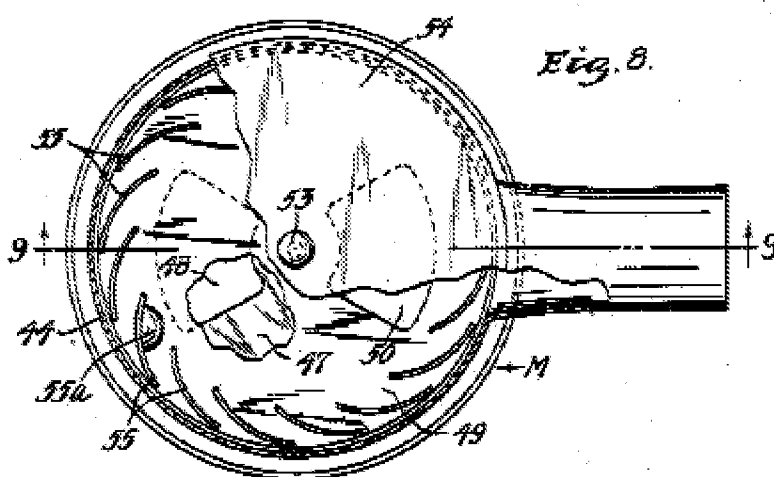
a cover (54) capable of placement over the wound dressing member (44) to seal about the wound and create a sealed environment (45) between the wound and the cover (54) in which negative pressure can be established (see fig. 9, *infra*)(col. 3, line 1).

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Regarding claim 13, La Mere discloses that the insert body (M) is cylindrical or rod-shaped (see fig. 8, *infra*).

Regarding claim 16, La Mere discloses discrete passageways (24).



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Regarding claim 19, La Mere discloses that the insert (M) is rubber, not an adhesive material.

Regarding claim 23, La Mere teaches a wound insert that is capable of preventing an ulcerated portion of a wound from forming a bridge to another ulcerated portion of the wound.

Regarding claims 24 and 25, La Mere discloses a non-porous rod-shaped insert (M).

Regarding claim 27, La Mere discloses a wound insert (M) with a plurality of rods (23) held together by a web that can be torn apart.

Regarding claims 28 and 29, La Mere discloses a central conduit (24) in communication with surrounding conduits via chamber.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 9-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lockwood.

Lockwood does not disclose expressly the claimed sizes and shapes of the absorbent insert.

Mere changes in size or shape are not sufficient to patentably distinguish an invention over the prior art absent a showing of criticality. See *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Furthermore, Lockwood teaches a dressing insert (20) that can be cut to fit the size and shape of a wound (¶ 0032).

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At the time of the invention, it would have been obvious for one of ordinary skill in the art to provide the wound insert of Lockwood in any size or shape that corresponds to a wound to which it is to be applied.

Regarding claim 10, see ¶ 0032.

Claim 15 is rejected under 35 U.S.C. § 103(a) as being unpatentable over La Mere.

Lockwood does not disclose expressly the claimed size of the insert.

Mere changes in size or shape are not sufficient to patentably distinguish an invention over the prior art absent a showing of criticality. See *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Response to Arguments

Applicant's arguments filed 15 August 2008 have been fully considered but they are not persuasive.

Regarding the rejection of claims 1 and 27 under La Mere, applicants assert that La Mere does not disclose a cover over the wound dressing. Element 54 is a cover that is placed over the treatment device/site. Vacuum is provided to the chamber (45) above the treatment site.

Applicant's arguments with respect to claims 1-7, 9-16, 19, 23-25, 28 and 29 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. BOGART whose telephone number is (571)272-4933. The examiner can normally be reached on M-F, 10-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Bogart/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761